NACDS

National Association of Chain Drug Stores

March 29, 1999

Dockets Management Branch (HFA-305)

Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Draft Guidance for Industry on Placing Therapeutic Equivalence Codes on Prescription Drug Labeling (Docket No. 98D-1266)

Ladies and Gentlemen:

This letter comments on the FDA's draft guidance concerning therapeutic equivalence statements on drug labels. We appreciate and support the rationale of the draft guidance, which is to "contribute to the accurate and safe selection of generic products by pharmacists." 64 Fed. Reg. 4434 (Jan. 28, 1999). Placing therapeutic equivalence information on drug labels can be a convenient method of helping pharmacists determine whether generic substitution is appropriate. As discussed below, however, FDA should be vigilant in reviewing therapeutic equivalence labeling to prevent situations that may actually increase confusion among pharmacists.

Introduction

Founded in 1933 and based in Alexandria, Virginia, the National Association of Chain Drug Stores membership consists of over 130 retail chain community pharmacy companies. Collectively, chain community pharmacy comprises the largest component of pharmacy practice with over 93,000 pharmacists. The chain pharmacy industry is comprised of over 19,000 traditional chain drug stores, 6,800 supermarket pharmacies and nearly 5,000 mass merchant pharmacies. The NACDS membership base operates more than 31,000 retail community pharmacies with annual sales totaling over $135 billion including prescription drugs, over-the-counter medications and health and beauty aids. Chain operated community retail pharmacies fill over 60 percent of the more than 2.78 billion prescriptions dispensed annually in the United States. Additionally, NACDS membership includes more than 1,400 suppliers of goods and services to chain community pharmacies. NACDS international membership has grown to include 90 members from 22 foreign countries.

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413 North Lee Street, P.O. Box 1417-D49, Alexandria, Virginia 22313-1480 Phone: 703-549-3001 Fax: 703-836-4869 Web: www.nacds.org

FDA has concluded that present law already allows manufacturers to place therapeutic equivalence information on drug labels. See draft guidance at section V, n.3. The draft guidance merely provides recommendations for labeling; it "does not create or confer any rights for or on any person and does not operate to bind FDA or the public." 64 Fed. Reg. 4434 (Jan. 28, 1999).

The draft guidance suggests that labels may compare the equivalence of drug products by providing the applicable equivalence code from the Orange Book. For example, a label may state that the drug product is "AB" to another therapeutically equivalent product. Conversely, a label could state that the drug product is "BX" to another therapeutically inequivalent product.

Potential Confusion

NACDS is concerned that some therapeutic equivalence statements may actually increase confusion among consumers, pharmacists, and other health care providers.

Our initial concern is that drug labels are already too crowded with information. Additional copy on the package will cause visual clutter. FDA recently recognized that fact when it permitted the removal of the "caution" and "warning" statements to relieve label clutter and make labels easier to read.

Moreover, a manufacturer could opt to reduce label crowding by listing on a label only one of several products that are therapeutically equivalent or inequivalent. Incomplete therapeutic equivalence information may be misleading. If only one other product is listed as therapeutically equivalent or inequivalent, pharmacists could incorrectly conclude that FDA has not determined the therapeutic equivalence or inequivalence of other drug products that are not listed on the label.

Additionally, placing different brand names on a label may confuse pharmacists about which product is actually contained in the bottle. NACDS is concerned that this additional information could cause pharmacists to inadvertently dispense the wrong product.

Patients may also be confused by the therapeutic equivalence codes. The Orange Book codes are not generally known or understood by consumers, so they may be confused about the relationship between the various drug products listed on a label.

Moreover, in some cases the therapeutic equivalence codes are similar to clinical shorthand terms. "BP," for example, is both an Orange Book code and a symbol for blood pressure. That could lead to medication errors by patients, as well as errors by health care professionals such as nurses, physicians, and physician assistants.

At a meeting of the National Coordinating Council for Medication Error Prevention and Reporting on March 18-19 at USP, Jerry Parrish (the FDA's contact person on the guidelines) discussed the FDA's concerns regarding therapeutic equivalence labeling. Mr. Parrish indicated

that the draft guidelines were produced because FDA is concerned about improper substitution of drug products that FDA has not determined are bio-equivalent. That is a legitimate concern, but it is limited to a few easily identified drug products. If the FDA has concerns about a few products that pose a substantial risk of improper substitution, then the guidance should be limited to those particular products.

Conclusion

In light of these concerns, NACDS believes that FDA should conduct studies to determine whether the new labeling may confuse pharmacists and consumers. Testing is needed to evaluate whether the new labeling will increase medication errors.

Thank you for considering our concerns when FDA finalizes the draft guidance. Please call me or Don Bell, Director of Federal Regulatory Affairs, at 703-549-3001 with any questions or comments.

Sincerely,

S Lawrence Kocot/bxd

S. Lawrence Kocot
Senior Vice President, Government Affairs
General Counsel